

Christi Keene: Welcome, everyone. Happy Monday. It's great to see so many people joining us today. We have a wonderful agenda for you today. But before we get to that, just to note, we received many questions via the registration, so thank you. And we'll do what we can to respond to those. But if we don't speak to your question or comment specifically, please use the Q & A feature in Zoom to ask a question. Now let's do some brief introductions and opening remarks.

My name is Christi Keene. I'm a Senior Director of Research Finance at the University of Chicago and co-chair of the Finance Audit and Costing Committee with FDP. Before I hand off to my colleague Melissa, I want to say again, thank you for everyone for being here and sharing your time with us today. And a sincere thanks to all of our NIH partners who are on the call today. This is really a testament to their commitment to the FDP NIH Data Management and Sharing Pilot. We greatly appreciate your time and the time of NIH devoted to this pilot. Melissa, I'll hand off to you.

Melissa Korf: Thanks, Christi. Hi, everyone. I'm Melissa Korf. I'm Senior Director for Research Contracts, Data and Security at Harvard Medical School, and I'm also the co-chair of the Research Compliance Committee with the Federal Demonstration Partnership. Now I'll pass it off to Jim to introduce himself.

Jim Luther: Thanks, Melissa. Good morning, everybody. Jim Luther from Yale University and also co-chairing along with Melissa and Christi. Delighted to have so many people join us today. And Michelle, I'll hand it off.

Michelle Bulls: Good morning, everyone. We're so glad and grateful that you're here with us. I'm Michelle Bulls. I am the Director of the Office of Policy for Extramural Research Administration. I also serve as NIH Federal Exec for FDP and serve as Christi's co-chair in the Finance Audit and Costing Committee. I really am excited about having the town halls. I love interacting with you guys, and I really look forward to really frank, candid, and open discussions. I echo Christi's sentiments about the fact that we will try very hard to get to many of the questions that I know you guys have. We are ready to answer them. And so, I'm going to kick it off.

And second of all, I want to thank all of my NIH colleagues for joining both program officials and OSP and others. And I also am joined by my deputy Kristin Ta. You guys know Kristin. We call ourselves the dynamic duo, and we are excited to be here to serve alongside of Christi, Melissa, and Jim. So thank you so much. Back to you, Christi.

Christi Keene: Thank you, Michelle. All right, let's take a look at the agenda. So, we'll just today do a brief pilot background. I'm sure many of you have seen and heard this before. We'll do some updates on phase one of the pilot. We'll give you some, kind of, behind the scenes of the round tables that we've held. And a brief update on DMP tool for those that use it. And then we will make our sales pitch so that if you would like to join the pilot, you are welcome. And then

we will save ample time for Q&A, in the event that we don't get to those, we do have many of them that we've received ahead of time, so we'll do what we can.

All right. So just a little bit of background under the new NIH policy for Data Management and Sharing, each institute and center has the flexibility to develop requirements to meet the needs of their particular field. You know, this significant variation in requirements could place a substantial burden on researchers to navigate that requirement before they even submit their proposal that can be difficult to manage. So, the FDAP NIH Data Management and Sharing Pilot is a collaboration between the Federal Demonstration Partnership and NIH. We've engaged with the ICOs, the Office of Extramural Research subject matter experts, and the Office of Science Policy and OPERA and Compliance to roll out this pilot.

So main goals are to generate greater consistency in plan requirements across the ICs. And with that, we aim to mitigate the administrative burden for researchers and those who support them associated with the plan development and implementation. So we have divided the pilot into two distinct phases. We are currently in phase one, which is the template pilot. We're testing the effectiveness and the usability of two templates. These templates were developed by our NIH ICO colleagues. This was a collaboration amongst them to determine what do they need to see in a good plan. So from that, we have our two templates, the Alpha template, and that is a more prescriptive plan designed to limit the need for free text. So a lot of, kind of, smart questions, if yes, then you get another question.

And then we have the Bravo template, and that provides some more detailed prompts. It's, kind of, the hybrid between Alpha and the sample format. So you get some free text, but you get some prompting as well. So from the use of those templates, we're gathering data from researchers and those who support them on what was their experience? What did those templates provide to them that maybe the sample format didn't? How did it help them to prepare a better plan? We will use the information, we gather in phase one actively gathering that data now. So we will use that to inform phase two, which is the cost policies. We have a lot of questions in the registration today related to cost, to budgets, and we will address those. But look for more information to come from phase two of the pilot. From there we can establish some common cost principles. We want to identify types of cost required and determine how to identify additional costs that may be required to meet the spirit of Data Management and Sharing.

So, we are in the planning phase now. We plan to roll out phase two towards the end of this calendar year. So phase one we kicked off in March. Doesn't sound that long ago, but it feels like we've been doing this for a long time. We've become very familiar with those templates. And since then, 20 institutions have formally agreed to join the pilot. We are very grateful for their participation. and we are allowing that because these templates are publicly available, anyone can use them. We do ask that anyone who uses them still provide feedback, because that is very valuable. Any information that you can share about your experience using the templates is valuable, whether you're a pilot institution or not. And we recognize that being a participating

institution comes with it some, you know, additional responsibilities. And we recognize that, you know, it may not fit for everyone but we are extremely grateful for those who have joined.

And we have some, kind of, additional perks of being a pilot participating institution. At the time that we rolled this out, March, you know, wasn't a huge proposal deadline. You know, we were, kind of, post January 25th. And you know, we recognize that June and July are big proposal deadlines and we'll be getting a lot more usage. We have seen a lot more data come in just from those two deadlines. And I anticipate, you know, it's only July 17th. We'll be getting a lot more feedback from that July deadline. Okay, now we'll hand it off. That's to you, Jim.

Jim Luther: Thanks, Christi. Thanks, Christi. So just a quick update on the round tables and the town halls. We've had two round tables. As we discussed, or Christi mentioned, this is one of the most significant benefits of being a member of the pilot of the pilot group, these are structured informal, casual way. We send out a handful of questions in advance to kind of stimulate discussion, but then it's just, kind of, a free for all a discussion between Michelle and Kristin and members of the ICs. And along with Melissa, Christi, and myself. I think, we've had about seven or eight institutions, probably a total from those seven or eight institutions of, I don't know, 20 to 30 individuals really good discussion. Probably a lot of the same things that'll come up today, but a really good opportunity to talk in a very conversational way with Michelle and Kristin [INAUDIBLE] that are coming up.

And thus far it's been good discussions about selection of repositories things like uncertainty about selecting how to identify the type of data early on in the stage, especially for new investigators. Some philosophical discussions about why is NIH rolling out the data management and sharing plans? What is the importance of making data available from the standpoint of public sharing of data rigor and reproducibility? Those types of things. But really getting at the core of driving how faculty and investigators can develop these plans in a way that meets NIH's needs, as well as the importance of the science. There was some discussion about making data publicly available and animal rights groups, and does this put investigators at some level of risk because of the public nature of the data. Also other things around the data, specifically, answering elements of the questions, differences between the two different forms and so forth. So really good active discussions [INAUDIBLE]. We've had two of these, taking a little time off for the summer, but we anticipate more in the fall.

The second is one quick slide just about today. I don't think I have much to say because Christi has gone over this, but this is an open forum, right? I think we've had somewhere in the neighborhood of 600 or 700 people sign up. This is where we encourage you to invite people from the library if appropriate, from departments supporting individuals, certainly faculty the more faculty the merrier. But everyone that might be involved directly or indirectly supporting the plan is what we really want from these. And as you can see on here, it will be recorded and posted on the website. So happy to now turn it over to, I think, you, Melissa. Thank you.

Melissa Korf: Thanks, Jim. So just wanted to mention a little bit about some of the resources that we have available on the FDP Pilot website. And thanks so much for posting the link in the

chat there, Kim. There are a lot of resources that are available on that website now as well as we scroll all the way to the bottom the email address to use to contact Christi, Jim, and I. And we receive a lot of great suggestions for resources to add to the website. So please, if you've got a suggestion for something that you wish you saw and, you know, wish you thought would be really helpful. Or either in navigating your policy or in, you know, considering participation in the pilot or giving the templates a try, please don't hesitate to let us know.

As we're able to work through those requests and add resources, we're doing that.

So some of the resources we have already is slides and video from presentations and meetings. We are cross-posting the link to slides, materials and recordings from these sessions. The DMS plan templates both in format, which has some notes and a clean copy are available via the website. As well as some of the reporting templates that we're asking institutions to use, a quarterly reporting template, as well as a link to the more faculty researcher focused Qualtrics questionnaire. We are putting the finishing touches on a second version of a questionnaire that's really more targeted towards research support service providers. So librarians or folks in research computing. Who from their support of researchers have feedback to offer on the templates, but may not have been filling out a template in the same way as a researcher or a PI. So we're working on adding additional resources as we're able to create those. And welcome any feedback you have on what would be helpful.

I'd also like to provide a little bit of an update on DMP tool. You know, we've had a lot of questions come up as to like, "Well, are the templates available in DMP tool? Are they going to be available in DMP tool? Why not just use what's already available in DMP tool?" And so we're really excited to share that both Alpha and Bravo are now available in DMP tool. They were there about a month and a half ago as of early June. Some of you may have seen them already. Some of you might be saying, "Well, what is DMP tool?" It's a free open source community supported application that's been used for about 10 years to create data management plans. Anyone who would like to use DMP tool is able to create an account and access the templates.

Some institutions have become members in the sense that they, you know, leverage single sign-on or might have institutions specific guidance into some of the templates. But even if your institution isn't a member in that way, you're still able to create an account and use the resources that are available there. There is some great functionality in DMP tool that allows a researcher while they're working to create the template to share, or sorry, when they're working to create their plan, they can share that plan with their data librarian or other folks to receive support in completing various sections. They also have funder specific templates you know, one for NSF, one for other certain non-federal sponsors. You can go into DMP tool and select your funder and receive some specific templates. As well as just general best practice guidance.

One of the other things that we're really excited about is that DMP tool provides the ability to create a persistent identifier, a DMP ID for a data management plan. Which really helps with linkage of products of that data management plan back with the DMP. And, you know,

potentially could provide a lot of helpful functionality in tracking outcomes. So when you log into- oh, and, I think, this image might be a little bit outdated, so apologies for that. It's, sort of, a last minute update. If you go into DMP tool right now and select NIH as the primary funding organization, you'll see three different options. And it used to be that the name of the, sort of, standard NIH template that was created based on the sample format page and published NIH guidance was just NIH GEN DMSP. And we received some feedback that it would be preferable to have that one appear first. And so the title of that has actually been changed to start with default. So now you'd see the default NIH GEN DMSP first in the list, followed by FDP Pilot template Alpha FDP Pilot template Bravo. And all three of those are valid options to use to create your data management plan.

Just one more comment. We've received a lot of questions about, you know, when should we use one versus the other? And, you know, why wasn't the DMP tool template the default for the NIH GEN? I'm sorry, I don't know what just happened to the slides. But why wasn't the default or the NIH GEN template sufficient? And so one issue with a narrative format data management plan, which is what the sample format page is designed as, it's a very narrative format. As well as a lot of the templates within DMP tool as it is are narrative format. It can be very hard and I, from experience, you know, we've gone through some of our- the prior slide, please. We've gone through some of our own- my own institutions DMP's and been trying to pick out some information. And it can be really, really difficult to pick out information like repository, data type from a narrative format. You're, kind of, hunting and picking for the information that you're looking for, and sometimes it's not there.

So the hope with creating Alpha and Bravo, I think, from, you know, not to put words in our NIH colleagues mouths, but you know, what they've shared with us is that, you know, this will make it a whole lot easier to make sure that PIs, researchers are providing the information that the program staff will need in order to evaluate and improve the plan. So it makes it really easy for researchers to go through, sort of, that template, almost using it like a checklist. You know, "I provided that, provided that." And then for a program officer to easily identify the information that they need. So that was the thought behind creating Alpha and Bravo.

As well as just generally a more standardized template will enable us to collect standardized data and run reports, which repositories are getting a lot of use. What are the highest volume data types? And things like that. In terms of Alpha and Bravo, there isn't a preference one way or the other. They are slightly different in that Alpha is very structured and Bravo is more structured than the sample format page. But still, you know, offers some free text entry, a little bit more flexibility. And what we're really trying to test is, are these the right standard format or standard data fields? You know, is there something missing? Is it asking for too much? Which is the right approach? How much structure is going to work in these templates? So there's really no preference whether or not you choose Alpha or Bravo. You know, we hope that people will give both a try and send us your feedback in the Qualtrics questionnaire to help us help NIH arrive at the most user-friendly, effective template possible out of the pilot.

We are so excited that we're able to offer the templates and DMP tool now. We had heard from a lot of institutions that that was a hurdle for participation, that they had really, kind of, invested in using DMP tool and encouraging use of DMP tool. So that would be a hurdle to participation that they hadn't been in DMP tool at the start of the pilot. So now they are, if that changes your ability to participate, we would love to have you join us. And our email address is on this slide. And I see that Kim also popped it in the chat. Thanks, Kim. Send us an email if you're able to participate now that the templates are in DMP tool.

We also understand that the quarterly reporting requirement has been a little bit of a hurdle, and that is something that is really important. It's really critical to helping us get the best data that we can. There is a lot of utility to using the template and filling out that Qualtrics. So if that's all you're able to have your researchers do that's great and the feedback will be really helpful. But what will be most helpful is for us to be able to, kind of, follow up. "Okay, so you submitted using this template. We got that feedback on the Qualtrics questionnaire." And then we can follow up and say, "Hey, just in time, how did that go? Did you have to make a whole lot of changes? Did you get a lot of questions?"

We'll also note that participation is not limited to FDP member organizations. We want to make sure that we're able to get a representative sample. And we recognize that, you know, FDP institutions may not fit the bill fully for making sure that we have a fully representative sample. So even if you're not at an FDP member institution feel free to reach out to us if you think you'd like to participate and we can send you more information. So, I think, that is the end of our, sort of, prepared remarks for today.

We really wanted to make sure that we could leave a lot of time for Q&A and discussion. I see that we've had a whole bunch of questions in the Q&A already. And if you have a burning question that we haven't gotten to please share that with us. And we'll do the best that we can to answer the questions in the Q&A. Or if we're not able to get to it today, or we need to take the question back to other resources to develop a really good answer, we'll make sure that we follow up.

Jim Luther: Michelle, I think, before we jump into the questions that we wanted to see if you had some additional thoughts from NIH's perspective.

Michelle Bulls: It'd be nice if I could click off of mute. Thanks Jim, and thanks, Melissa and Christi. So there are a couple of things that I would like to share. Just because, I think, it's important for us to keep everyone abreast of, kind of, what we're doing here on the NIH side. And so I know we've had a few presentations at FDP and elsewhere. And we've also talked about it a little bit in other town hall forums and settings. But NIH we have reviewed the single line item budget policy, part of the DMS policy. And agree with our colleagues, you that this may place both the recipient community at risk as well as NIH at risk. Because you all are putting budgetary information in a single line item that where it does not identify or compute with the cost categories as outlined in the cost principles.

And so we are actually actively finalizing the guide notice that will roll back the DMS single line item instructions, and that would be effective October one. And we absolutely expect to have that guide notice out this week. It is going through leadership review and clearance. And I will also let you guys know that the concerns and the challenges were heard loud and clear. We've also seen various ways of which folks are submitting the budgets. Some are absolutely doing it the way that the cost principles require you to, which is to put it in the appropriate cost categories, which is totally fine. And we will be addressing that piece in the guide notice as well. Just to let you know that while it is effective October one, we will not be, you know, requesting for folks to resubmit budgets in a single line item prior to October one.

And, I think, that's really important because we want to make sure that we provide adequate coverage for the community in this space. Since there's been a great deal of churn and consternation around it. The other thing that I think is really important for us to communicate to you all is that when we talked about the fact that we wanted to provide flexibility and making certain that, you know, we were not punitive in areas where folks may have missed submitting plans. Or NIH may not have been as clear in the notice of funding opportunities also known as NOFOs. You know, in the government we like to use a lot of acronyms. So what we have been saying though is that we would provide that flexibility. And just for you, in full transparency we have identified, you know, several areas where recipients or applicants have not submitted information, or at just in time. or it was not addressed properly in the NOFO.

And we are taking full responsibility in making certain that we identify the fact that there will not be any kind of punitive or compliance requirements against the applicant community. But that we are identifying there are some areas in the notice of funding opportunities we may have missed. And we are very much supporting that. And I wanted to say that because I think it's important as Dr. Lauer has mentioned many times that there would be flexibility. And understanding the fact that we are committed to that model. I just wanted you guys to know that that is something that we are definitely committed to. And so if you hear of anything where someone is asking for additional information and you have questions, feel free to reach out to the IC and reach out to others within OPERA if you need to. Because we do want to make sure that we are set, you know, being very consistent in our communication. Even if you reach out to the eRA help desk it is important for all of us to be singing from the same sheet of music.

So, I just wanted you to know that the instructions for the costs are being updated. And we will be making sure that we are very clear that the applicants need to still include details in the budget justification, including estimated costs of DMS costs, just so we can track that a bit. We did speak with our colleagues which are the FDP co-chairs to see if that would be a challenge. And we got the sense that that would be doable. We didn't want to place any undue burden on the community. But, I think, the end game and the baseline and core reason for why single budget line item was requested it's because we wanted to track. So we didn't want to lose, you know, that sentiment. So we're asking for estimated costs and the detail budget justifications for DMS costs.

I also just want to, before I go into another topic about DMS and things that we're going to be doing internally later this summer. Kristin, did you want to add or take away or correct anything that I might have said related to the cost policy?

Kristin Ta: No, I think, you hit on it well. And like you said, we're definitely not looking to penalize anyone for things where our instructions maybe could have been clearer or better. So we're definitely looking to make that easier for everyone.

Michelle Bulls: Sounds good.

Melissa Korf: Michelle and Kristin, we have had a couple questions popped in the Q&A on that topic. If we want to take those before we move on to other questions. One question is, where will the new crossing info be communicated?

Michelle Bulls: If we could just talk a bit about what we're going to be doing, because I wanted to give a few opening comments before we get into the questions. Because I think we need to sail straight through the questions if that's okay with you. Okay. All right. And so later this summer, one of the things that we just wanted to really quickly touch on is to let you guys know that colleagues within OER will be holding recurring meetings with our program officials across the enterprise. To discuss trends and what they're seeing and their plans as they begin to work up these awards. The goal really is for us is to evaluate the effectiveness of the policy. And to make sure that where we might need to make some modifications across the policy, we would work with, of course Office of Science Policy. But in the area of cost principles and justifications and making sure that the RPPR information, we understand what information we need to collect in the RPPR at some downstream point.

We want to really get a lot of good feedback from our program officials and the enterprise on the FDP templates, as well as the general template. And to have that, sort of, comparison, we want to see what they're seeing and evaluate that from a compliance standpoint. And really understand and try to figure out how much back and forth is going to be going on between just in time and getting those plans approved. And just to see if there are other things that we can do to help facilitate that from a risk management tool assessment standpoint, which are our internal checklist questions. Or if there is additional staff guidance that we need to provide to mediate that a bit. Or if it's really necessary because it fosters a really open, and healthy, and robust dialogue between the recipient, you know, the PIs and the program officials. To understand what we really are asking for and to really leverage some of that information that we're getting from the community.

That would be another thing for us to be assessing as we are, you know, looking at that back and forth dialogue between the program official, and the PI, and faculty. And then helping us to really understand whether or not the costs, you know, are we really getting the true estimation of costs? Are the costs reasonable? We know that they're probably going to be allowable, but we might need to be thinking about information that we should put in the NOFO that will outline nuanced costs that we are seeing that's being identified with DMS, right? Because those

might not be costs that we would normally provide for. And folks might ask, is that allowable? And we want to provide that coverage as well.

So I just wanted you guys to know that we are internally going to be looking at that. As well as trying to be very proactive in looking at what kinds of information we need to capture at the RPPR stage. So that the community understands that NIH is not just asking for this information and it's going into a black hole somewhere. But that it is information that you guys will report on and we would make available with some of the nuances in mind that you all talked about earlier Melissa, Christi, and Jim. And that is how is that going to impact, you know, animal information and requirements. And how will that, you know, impact the community on providing sensitive information in the RPPR and that kind of thing.

So we are going to be looking at all of those various points. And hopefully, be able to come up with some really good tools across the enterprise, working with a lot of folks within NIH to make that happen. So Kristin, did you have anything else to-

Kristin Ta: I think you hit on all the points that we had really wanted to get to. So I don't know that I had much to add other than that we're really looking forward to these discussions and we think it's really going to build upon, kind of, what we've started so far with our FDP colleagues.

Michelle Bulls: Yeah. All right. And so with that, I'll turn it back over to you, Melissa, so that we can start with the questions.

Melissa Korf: All right. We have some great questions in the Q&A, but, I think, I'll start with the questions that are in follow up to those comments. And so there was a question about how new information on the costing guidelines would be communicated. And when you think that that might be coming out.

Michelle Bulls: So as we stated, the information will be in the guide notice we will provide the instructions in the guide notice. And we're doing that until we can update our forms packages. And we were very clear that we needed to put as much information in the guide notice and as much instruction in the guide notice so that folks would know what to do. This is really just going back to what we were supposed to be doing in the first place. So we don't want to confuse anyone. This is just really about moving away from the single budget line item. And making certain that folks are putting- if it's personnel that's helping with DMS, putting that in the personnel space. If it's equipment, put it in the equipment space. If it's supplies, put it in supplies. Nothing new just going back to what we should have done in the first place. And we really need folks to just understand that we're undoing something that we created so that we can go back to the normal way.

Melissa Korf: And do you anticipate that any financial reporting requirements would be added to report on actual expenses incurred?

Michelle Bulls: So I wonder, you know, we've talked a little bit about that. And, I think, that that's going to be, honestly, I think, that's going to be a discussion and a learning curve that we're just going to have to continue to grapple with. Because what we think might be estimated,

and that's what you request in your budget, you get that and you need additional. I think, that's where, you know, the discussions go back to talking to the IC. And determining what the IC is able or unable to do. And then actually, capturing that maybe even in the RPPR at some point where we identify how much was actually spent. And even though you had to rebudget to do it and it didn't turn out to be a change in scope. But it definitely was, you know, greater than 25% in that single line item we might need to capture that. And so, Kristin, that might be something that we write down too, because, I think, that that will be important. Otherwise, I'm not sure how else we would capture it.

Kristin Ta: Yeah, absolutely.

Christi Keene: I'm sure we'll get more budget questions but maybe we can jump to some of the logistical questions we're getting in the chat around the pilot. So there's a question on, "How are institutions participating in the pilot providing quarterly reports?" So for those participating in the pilot, there is an identified person that we're working with at each institution. So that person, or in some cases two people have the quarterly reporting, it's an Excel file that the institution is using. You know, I think, this is- it's an important part of the pilot to get that feedback recognizing that every institution, kind of, operates differently. And so how each institution is getting that feedback is up to them, what works best for them.

So that is captured in an Excel file and we collect those. And then, you know, we, kind of, look at the feedback that we're seeing in the Qualtrics survey versus what's on the quarterly reports. And figuring out, "Okay, so it looks like the quarterly report, 10 faculty members submitted using templates, but we only had feedback on five." So hoping to, kind of, check and balance that qualitative feedback that we're getting in the Qualtrics survey. And there's another question.

"If one of the FDP templates are not used for a data management sharing proposal, will the proposal be rejected?" No. We want everyone to use the templates, but the sample format is still accepted. We've talked to institutions that have developed their own templates. What's important about the data management and sharing plan is that you're hitting on those six elements. The format, you know, while we anticipate that there may be a template at some point in the future. Currently, the format is not the most important thing. It really is addressing those six elements. So plans will not be rejected because they did not use a template. I think, there was another one, Melissa, if you see it.

Melissa Korf: Maybe this one, "What if my institution is not a participating institution, should we use the NIH GEN template? And would these templates differ between the type of applications?" So even if your institution is not a participating institution, the templates are out there, so they're valid to use in your submission. We do ask if anyone gives one of the pilot templates a try that they fill out the Qualtrics questionnaire and share some feedback with us on their experience. And, I think, I posted a response to one question earlier that we are working with DMP tool. We all want to add a link directly to the Qualtrics within DMP tool

somewhere in the books of the pilot templates to make that a little bit easier. But the Qualtrics questionnaire is available from the pilot website that's been- the link has been shared.

So, you know, just because you're not a formal participating institution, you would be able to use those templates. And, I think, the hope is that, you know, the templates don't necessarily vary between types of applications. The one possible exception might be- one of the things that we've talked about is, well, it's possible that it would be appropriate to have one template for human subjects research or clinical trials. Versus not human subjects research. So, we're hoping for, you know, really objective criteria for when you might select one template versus the other. Not because you're submitting to this IC or that IC. Or you're submitting an R01 versus a P01, you know, really things that are related to the nature of a project or nature of the data.

Christi Keene: There's also a question about, "How is the FDP team monitoring feedback from the first round of grant submissions to inform template refinement?" I think, we can look at that as FDP team NIH team collectively. Yes, those, you know, those proposals have now gone in. They are working their way through the process. So that front end feedback from the researchers, that's what we were just talking about, the Qualtrics survey. You know, we are reviewing that and, you know, hearing from the researchers. We're also hearing from the researchers directly in those round tables that are by invite only for participating institutions. Those are some valuable feedback that we're getting, what was the user experience with those?

And then on the other side, you know, waiting to hear from our NIH colleagues, what was their experience in reviewing the sample format, or Alpha, or Bravo. That's the valuable feedback that we will be seeing soon, undoubtedly with JIT happening in the coming weeks or months. So, I think, you know, getting through this, kind of, first round is very important to all of us. And being able to, kind of, iterate and refine that.

Jim Luther: Michelle, that's a bit of a theme, because this is another question about, "I've heard that a rubric or rubrics will be used by the NIH ICOs for reviewing the plans. Can you share more detail?" I mean, any initial thoughts or observations about the plans?

Michelle Bulls: No, I think, we all agreed that this is just way too early to determine, honestly. And, I think, if there were initial feedback, I'm not sure how helpful it would be at this juncture. Recognizing that probably later in the summer or toward October, we can have full blown discussions about it. And actually, add the POs as panelists to this. Because they will have seen a lot that we just, you know, have not been able to capture just yet. And so, I think, that the very nature of the town halls, we're in it with you guys for the long haul, no pun intended. But the town halls will shift over time, right? Because then at that point when information comes in, we'll be able to add our FDP pilot POs that can really give us a lot of good feedback about that. So, you know, the town halls will become even more creative and more informative in that way.

Christi Keene: And maybe-

Melissa Korf: Oops, sorry, go ahead.

Christi Keene: Just to add, it maybe speaks to some of the comments we've seen in the

Q&A. You know, when we first, kind of, started our meetings, our working group meetings to think about what does a template look like. You know, I think, the one thing we all agreed on NIH, my institution, others, we all agreed that the sample format that template is, you know, definitely hits on the elements required. But from an institutional perspective, you know, we like to gather our own data. And being able to analyze that data. What repositories are being used. What data types. All of that is very hard to pull out of a narrative format. And, I think, likewise, on the NIH side it's hard to pull out that, kind of, big picture data of what the plans are saying. And so the templates part of the goal is to be able to provide some, sort of, data that can be analyzed by institutions, whatever system you do that in. And then by NIH as well. You know, the sample format if filled out correctly just like the templates aims to address the elements. But the long term we would like to be able to use what we're learning from those templates to do better and to provide better resources for our researchers.

Jim Luther: I think, that's a good point, Christi. And, Michelle just to follow up on your point, it was phrased as a question, but I'll make it as a statement based on what you just said. There was a question, "Will NIH be adding FAQs, tips, et cetera based on data receive from Q1 and Q2? What about list of common errors, issues, and so forth?" You, kind of, answered that, but that might be a good idea as you get more and more data, turn it into tips, and issues and things to avoid, things to do well, and so forth.

Michelle Bulls: Absolutely. And, I think, that's the beauty of this, right? Is that we will have an opportunity to gather information. You know, we need to analyze it to determine whether or not it is the best tip. And if it is something that we would want to use. Or if it's something that we don't want to use and what that looks like. And that's going to be a real eyeopener, I think, for all of us.

But, I think, we're going to see that it's going to be very different based on, you know, the research discipline based on the IC. I think, that's where we're going to see some of the differences. And that will help us understand and the community understand the need for a little bit of that flexibility. But the other piece too is we're getting a lot of questions. I mean, even in the chat now where we're going to have to update FAQs. Because some of the things that folks are finding, those are real challenges that were not addressed directly in the policy but it does have implications. And so we want to make sure that they are identified and that the FAQs are addressed for the community.

Melissa Korf: So we've had one question in the chat that I think is potentially, a burning question for a lot of folks. We saw it in the submissions with the webinar registrations. And may not necessarily be directly related to our pilot, but it is potentially, related to other FDP activities. And that is a question on how PTE should manage sub-recipient compliance with the DMS plan requiring annual certifications, you know, what sort of documentation of oversight. And so, I can, sort of, provide some feedback based on conversations we've had with the FDP sub-awards subcommittee. And Michelle or Kristin, if I run astray or there's anything that you would want to add from the NIH perspective, please, we would love to hear it.

Michelle Bulls: Did you answer the question?

Melissa Korf: No, I'm about to. So that was my disclaimer that, you know, I'm answering from a different perspective.

Michelle Bulls: Yeah. And that's one of the ones that Kristin and I- I just said to Kristin, "We're going to have to do an FAQ." But I'd like to talk about it internally just to share what the requirements are and the flow down requirement. And what that looks like in this space because it looks a little different from other things.

Melissa Korf: Yeah. And just I will say that the FDP template does have the ability now to indicate that you're attaching a data management and sharing plan. And, I think, conversations with a lot of institutions suggest that if there is a plan, we would expect to see it attached to [INAUDIBLE].

Michelle Bulls: Melissa, thank goodness that's where we landed, wow. That's the only way.

Melissa Korf: So, from that, sort of, like institutional perspective, I think, it's going to be a best practice to make sure you're sharing that plan with your sub-recipients. And there's been, you know, a lot of conversation in the community of about does that happen at the proposal stage? When is the right time to do that? And again, in terms of, sort of, best practices from the institutional perspective, if the plan involves one of your sub-recipients, it's probably optimal to ensure that they can meet that obligation before you submit the plan. And find out at the award stage that they're not prepared to achieve something that's included within the plan. So, it's a little bit of an added burden because it isn't something that we have historically necessarily shared at the proposal stage. But it would be a good idea and absolutely- so would love to see what FAQs NIH is going to come up with but it's also-

Michelle Bulls: But to your point that, like, you're right down the street because this isn't something we would necessarily collect at that stage, right? We wouldn't expect you to collect it at that stage, but you can't get to the award stage and figure out that you're not going to be able to do it. Or you're not budgeted for it, right?

Melissa Korf: Right.

Michelle Bulls: And so that is a different model that I want to make sure that our internal leadership knows and understands. And then the folks that are working the DMS policy world understand as well that there are some grant regulatory requirements that are going to impact how this looks. And we need to be prepared to give the recipients, and applicants the enforcement, and the leverage that you need to get the information at the time that you need it. Because otherwise it's going to be a disaster.

Melissa Korf: But, I think, the FTP sub-award subcommittee has also been already, kind of, talking about, you know, "Would we want to add another, sort of, checkbox on to this standard letter of intent? To, kind of, cover our bases on this? Or is there any, kind of, tweaks to the sub-

award agreement template that would be helpful?" So definitely, some close collaboration with them on that topic.

Michelle Bulls: Is that something that we can maybe set up a meeting with you guys to meet with them on? Because, I think, it's going to be really important for you to get the NIH input as well.

Melissa Korf: Yes, absolutely. That would be great, Michelle. We would love to do that.

Christi Keene: Okay. So, we do have a few people with their hands raised. I think, we can facilitate unmuting Crystal Gustafson. I think, you can take yourself off mute if you would like to ask a question live. Or Emily Malone also has a hand raised. So, if either of you would like to- Oh, okay, false alarm. We'll go back to the Q&A for some questions. Let's see. There's a lot of them. Oh, we have another hand raised.

Michelle Bulls: There's a few we can get through that have been here for a minute. Maybe we can try to address those. So, one says, "Investigators with small grants example given R15, R03s have extremely limited budgets. What is being done to support them or to reduce the burden on them?" And so, I think, that's why we really need to understand what the requirements are. We have several activity codes that have budget costs caps, and this is something that has come up often enough.

We recognize that. And I'm not sure that we're prepared to do anything other than identify, you know, how much over budgeted these may be. And whether or not that, you know, it takes you outside of the R03, R15 and puts you in another category. Or if we need to be thinking about allowing for folks to think about additional costs requested, you know, ICS are- what we don't want to set up is a precedent that every time there's a over budget that the recipient community comes in for a supplement or administrative supplement that is really not doable nor sustainable long term.

So, I think, we have to just look at, you know, what this looks like and determine whether or not this causes a different activity code selection or how this really looks. But, you know, our budgets, you know, we're not going to be able to sustain giving a great deal of large administrative supplements and that, kind of, thing for these costs. And I don't think that that would be sustainable. So, we do need to look at what the requests are. And that's why we want to see it in each of the cost categories. Like, what's the cost? What's the estimate? And then identifying like we played around with that, toying around with the idea of identifying what really the actual costs were in the RPPR so that we can determine how this needs to be reconciled.

There's another one that says, "So with a single budget line item, the justification would still need to include a detail under a single category." And so, I'm going to try to answer this as best I can. We will not be requiring recipient applicants to put in a budget in a single budget category. The budget costs will be distributed amongst the cost categories. So, as I said, if it's an individual or curator, you would-

>> She's Frozen.

Jim Luther: Is Michelle frozen for everybody?

>> Yeah. She's frozen.

Kristin Ta: Yeah. I think, what Michelle was trying to get at would be that in your budget you would simply put them in the category that they would normally go in, right? So, if you have a data curator, you would list them under personnel and note that the time that they're spending would be on data curation. We would just ask that you note the DMS costs throughout the budget in the appropriate cost category. Rather than putting everything in that single line item as the instructions currently state. And I see Michelle is back and she's nodding so-

Michelle Bulls: Right. Yeah. Yeah. We've, kind of, confused folks because we're really just going back to what the original requirements are. So, if you could, you know, look at the cost principles, look at your internal guidance, you're just going back to what you were doing initially. And moving away from the single line item. And if we need to, you know, add some details about that let us know. But this should be fairly easy, and this is what the community asked for. So, I assume that everyone understands what this is supposed to look like.

The budget justification though is going to be in accordance with the category that you are requesting the funds in. So, you would put it in the appropriate category. I'm trying to answer the ones we know. But Melissa, and Christi, and Jim, there's a long question from Laura Pearlman, "Apologies for the very long question, but how can repositories participate in this pilot?" Do you see that one?

Melissa Korf: Yeah, and, I think, it'd be really interesting potentially to have more of a conversation, Laura. So, if you want to reach out to us on our email address, maybe we can discuss this one a little bit further. But the first thing that jumps to my mind is when we post that research support service provider focused survey, to share any of that feedback with us via that survey. We've been receiving a lot of different feedback, sort of, ad hoc. And that survey is our attempt to try to make sure that we can gather that all in one place. I also think that there are a lot of things that we would hope to maybe eventually, potentially do with the templates. But, I think, we're really focused on making sure that we've got the structure right and the data elements right for now. And then, you know, some of your suggestions like automatically having information repopulate when they select a given repository that could come later. But we have to make sure that we all agree on the data elements.

Michelle Bulls: This is another budget question. I bet you guys are not surprised about that. These are good questions though. "Do you anticipate a particular method to specify detail and DMP expenses within the request from within the respective and appropriate cost categories?" No, we don't. The same way that you request any cost, you would just identify it when it's a DMS cost. And just place the request in. And then in the detailed budget justification, provide an estimate of what you think that would cost. But it's no different from what you do with

anything else except for you're just labeling all DMS costs in your detail by budget justification. Whereas, you don't necessarily label other things.

Melissa Korf: And Michelle, we're getting a lot of questions as well in terms of when this change is effective. And, I think, you would probably say it would officially be effective when you post in the guide notice and provide an effective date, right? And you're looking to do that in advance to when you can publish the next forms package-

Michelle Bulls: Right.

Melissa Korf: To give people that earlier relief. I will own what my own institution is doing on this, in that, you know, we weigh the compliance risks of separating out personnel costs and the issues of that would cause for us in tracking committed effort. And that we're meeting our effort commitments and made the decision that we would keep personnel in personnel. Because otherwise, we just- so, you know, that is a decision that my own institution made-

Michelle Bulls: A very good one.

Melissa Korf: And I apologize in advance if we're running a fowl of the current rules. But, I think, that, you know, there are some decisions an institution might make now-

Michelle Bulls: So, I think, we talked about that though. And, I think, we said that we have to weigh the compliance risks. So, it's not really running a fowl, it's really protecting yourself against an audit. By which by the way, we, kind of, said that's what you had to do, but we recognize that you cannot do that, which is why we're changing it. And so if institutions are moving forward now with changing it, that's a compliance risk that you've weighed. And it'll be in line with where we will land in October when the old policy is taken down.

But it might be helpful if you guys, I don't know if you all have a best practices or FAQs. It seems like folks are really getting confused with the fact that we're just moving back to the old requirement. If you guys could help folks just understand that we're not adding a new requirement, it's really an old- it's really the right requirement. I don't know how to say it. That would be really helpful.

Jim Luther: The only difference is, Michelle, is you're asking in the budget narrative to define it.

Michelle Bulls: That's right.

Jim Luther: So if you have 50,000 in equipment and you have a \$200,000 sub, in the description, you might say, "We want to clarify that 5,000 of the 50,000. So \$5,000 is related to the data management and sharing."

Michelle Bulls: Correct.

Jim Luther: So the budget for equipment would be 50,000, but in the narrative it would say 5,000.

Michelle Bulls: 5,000.

Jim Luther: And if the sub- yep, yep. So again, we're going to budget like we budgeted for 50 years. The difference is in the budget narrative, there needs to be some explanatory detail.

Michelle Bulls: That's right. That's exactly right. You said it so eloquently.

Melissa Korf: We also had one question about, "What if the PI says that there are no DMS costs, do you still need to list that somewhere in the justification?" And I would say if your PI says that there are no DMS costs, I would ask some follow up questions. Because, I think, a lot of times what happens at least at my own institution is that researchers are not thinking of the very real, very significant personnel effort. Which has an associated cost that goes into cleaning the data and preparing it for deposit and things like that. So we're not really just looking at a repository deposit fee, which, you know, if you're using an NIH repository that may be free to deposit, right? We're really looking at everything else that goes into it so-

Michelle Bulls: Yeah, working up to the deposit, right?

Melissa Korf: Right, right. There is usually a lot of effort that goes into managing, for sure.

Michelle Bulls: Yeah. No, that's a good point, Melissa, as always.

Melissa Korf: And a couple questions about modular budgets. We're not anticipating any change to modular budgets, right? There would still be that separate justification required.

Michelle Bulls: Yeah. There's another question about the zero- I thought I saw that somewhere, Kristin.

Kristin Ta: Yeah, there was a question asking about having to list \$0 in the budget but that again, is going to go away with the elimination of the requirement for the single line item, as we said.

Michelle Bulls: And it goes back to what Melissa said, that if it's zero, you might want to ask some follow up questions anyway.

Christi Keene: Yeah, there is a follow up that, you know, if the PI says it's part of a position that exists on the team, and, I think, that's Melissa's point is that there is still effort involved. And to be able to quantify that, I think, is really important. This is one of the things we've talked about a lot as we're thinking about phase two of the pilot is, you know, it's really important that we have a representative group of participating institutions in phase two. Because we've recognized that the costs at my institution or the supports in place may look different than the supports in place at other institutions.

And to be able to effectively know what that is and then assign costs to it is really important. Because we know someone's effort is required and with that effort is a dollar amount. And I say that having read many of my own institution's plans that I, kind of, wondered if the budget was accurate. So, you know, we're learning and we're getting there. But that's why we really need phase two to be representative of the research community, not just a handful of institutions.

Michelle Bulls: There's a really good question here, Kristin and Michelle, "Will you consider having a town hall meeting with NIH, ICO POs or Cindy Danielson, which is one of the leads

under the Office of Extramural Research headed by Dr. Lauer? Sharing NIH's experiences in Q1 and Q2, DMSP submissions highlighting common errors to avoid, and some good examples that would be very helpful to the community." So this individual is a way in our brain because that's exactly why we're going to be engaging our POs later. Actually, it'll be next month. It feels like it's later in the summer, but, like, time is, like, on a- it's really fast.

So once we engage all the community, the PO community as well as specifically our FDP pilot communities our POs, we will be having that, sort of, proposing that question to the FDP pilot POs. As to whether or not they would be interested in doing town halls to share information. So not only would we be looking at this from an evaluation compliance standpoint. But actually talking to the community about what we're seeing. And giving the community an opportunity to ask questions of the POs. So this is, kind of, again, we talked about, kind of, how this town hall is going to morph and turn into so many different things over the course of this year. So I'm excited about that and I'm very grateful that you asked that question.

Melissa Korf: There's a really good observation that some costs related to DMS activities may not be direct cost to the PI, which is why they would indicate no cost. So if your library provides curation services at no direct cost because it's included in part of the IDC rate calculation or something like that. And so that's why I say I would ask some follow up questions. Because it is possible depending on, you know, what repository the faculty member is using and what support services are provided, you know, at no additional direct cost, zero could be a possibility. But, I think, that there's a lot of difficulty right now for researchers in trying to really think and wrap their heads around the full cost. So that's why I would say just asking some follow up questions.

And then there was another question about, you know, "If you receive a data set via a data transfer use agreement and the agreement contains a fee or, you know, reimbursement for the cost to transfer, what category would this go in?" And, I think, that the guidance that NIH has published right now is that the cost to acquire data for secondary analysis wouldn't be considered a data management sharing cost. I don't know, Kristin and Michelle if you can think off the top of your head. But I would think somewhere in other costs but not necessarily within the data management and sharing budget.

Kristin Ta: And I don't know if you saw us nodding, Melissa, but we do, I think, we would agree with that. Yeah.

Melissa Korf: And another comment in terms of cost and how difficult it can be for PIs and researchers to estimate the personnel effort. And thereby the cost for DMS activities is can be be really challenging. Especially for researchers that haven't ever had to create a data sharing plan before. And so, Stephanie, it is one of the things that we've, sort of, talked about. Is there some, sort of, a rubric or tool or something that FDP could look at in phase two that would help folks with creating those estimates?

Jim Luther: The only thing I'd add to that, Melissa, is if you remember when we did the survey, that was the number one most difficult thing. Is, you know, the notice is clear about reasonable allowable cost that can be included [INAUDIBLE] the curating data, local data management considerations, preserving and sharing. But that's really helpful. But getting into the details and really determining to your point, about data that's being acquired is an allowable cost, but it's not considered a data management sharing costs. That's one of a thousand examples that are really hard to distinguish.

Christi Keene: There's a follow up question. "If someone in key personnel will have responsibilities for study execution and also data management sharing, should their effort be specifically broken down by non-DMS and DMS tasks for the justification? With effort related costs assigned to the separate sections." So yeah, that's- it should be clarified that this effort is related to data management sharing if they, kind of, wear multiple hats.

Jim Luther: But in the future. Today there's ambiguity as to whether you would put some of that in the effort and some of it in single line. Post October one, if the individual's 50% on the grant, they're 50% on the grant. And in the budget narrative you would say that 10% of the 50% is related to data management sharing. However, NIH clarifies that, whether it's a dollar amount or percentage or something that's the clarification. And earlier, Michelle, there was a clarification or a question of timing. And again, I think, you said the notice is under development, but it's likely to go be effective post October one, is that correct? The single line clarification.

Michelle Bulls: Mm-hmm.

Jim Luther: Post October one?

Michelle Bulls: Yeah.

Jim Luther: Thank you.

Michelle Bulls: The notice will come out prior to October one though.

Melissa Korf: So there was a two set of questions that, I think, are interesting. Was a question about whether or not we're working with DMP tool, or whether NIH is working with DMP tool on their work on creating machine actionable templates. And, I think, that would be an interesting question for us to discuss the next time that Maria is able to join our weekly working group calls. But then a follow up question on that, kind of, talking about some of the utility of a more narrative format plan. Where, you know, the more narrative format plan really allows data librarians or, you know, support providers to gauge the data literacy of a researcher better than a more standardized template. And that may be absolutely true.

But, I think, that, you know, some of the conversations that we've had with researchers who were used to using the sample format page. And then we were trying to convince them to get the pilot templates a try. They were like, "I really have to pick a repository at the proposal stage? Like, there's a field here and I have to put an answer?" And yes, like, that is the expectation that you identify that repository in a DMS plan you're submitting with the proposal.

So, I think, you know, we're looking for that right balance. So absolutely, like, that's the type of feedback that's super helpful in terms of, is there a way to achieve the goal of making sure that, you know, the DMS plans include the information that's needed? That program staff are able to identify that information quickly and efficiently to know whether or not they need to ask follow up questions. As well as meet some of those goals. Is there a way for us to meet that happy ground? But, I think, one of the potential downsides of the narrative format is that it is really easy for a researcher not to provide the information that's necessary. And so, you know, anticipating a lot more follow up questions. And we'll see if the pilot data bears this out or not, right? But, I think, the thought is that we may see a whole lot more questions and follow questions for the narrative format versus a more standardized format. So, you know, there's blessings and curses to, kind of, either way that we would approach this.

Christi Keene: So I see another follow up regarding effort commitment, "Will the total of non-data management sharing and data management sharing, or would they be separate commitments?" And I'm talking post change, so post October one, the effort commitment say of the PI would be the collective of non-data management and data management. And then in the budget justification. So, I think, the example earlier was 50% and in the budget justification you would break that out. Again, that's post October one world. Or if your institution has maybe made a change ahead of that for compliance reasons, but they would be broken out in the budget justification.

Jim Luther: Michelle and Kristin, I hate to keep asking about the timeline for the notice because you've been very forthcoming, but there is a good question regarding the grant, the cycle three grant deadline starting on October 5th. And, "Will the notice come out early enough that people, you know, will it come out in early September or something?" I mean, again, not asking you to commit, because I know how difficult that is, but-

Michelle Bulls: I think, we said the notice would be out at the end of the week. I don't know what else to say.

Jim Luther: Oh, I'm sorry. I didn't hear that. My mistake.

Michelle Bulls: Yeah, I said it in my opening comments

Jim Luther: The end of the week?

Michelle Bulls: Yeah.

Jim Luther: Oh, great. Oh, wonderful. Thank you. Sorry I missed that. Thank you. That should be plenty of time. Thanks.

Melissa Korf: There have been a couple questions about additional guidance regarding sensitive data adding to the FAQs, examples of sensitive data, whether PHI or other human subjects data how to handle de-identification of data. And that might be an interesting one for us to explore a little bit in phase two as well. Anecdotally, Michelle and Kristin, we heard from one of our researchers that's using the qualitative survey data. But if he wanted to have his data certified

de-identified as might be required to deposit in certain repositories, but that costs about \$50,000 per project. And so potentially, really high cost for de-identification of data that's really hard to de-identify. And maybe looking at that or taking back to the Science Policy folks that there's interest maybe in more tips on handling sensitive data.

Kristin Ta: Yeah, we can definitely take that one down and take that feedback so that we can see if there's more guidance we can share.

Melissa Korf: We have one request for a budget justification example to be posted maybe, you know, alongside some of the sample DMS plans. I don't know if that's anything that NIH has been planning. Or maybe that's something that we could take a look at in phase two for FTP to pull together something.

Michelle Bulls: I don't see the question. You see it, Kristin?

Kristin Ta: Someone suggested publishing a sample budget justification when we update the guidance.

Michelle Bulls: Oh, okay.

Kristin Ta: Just asking for an example.

Christi Keene: Okay. So we just have a few minutes left. And I see many people are probably hopping to their next meeting. But, I think, if we can share some closing comments. What we've heard today, very helpful. All the questions those that we got to and those that we didn't, great to hear from the community. Additionally, those who provided questions in the registration we know we have work to do. So thank you for that.

But really just thank you to NIH, to all of our partners who have been very active participants in all of this. And sharing all of this information with the community. It's very helpful. And we know that the pilot is already proving itself. A lot of what we've been able to share today is because of questions that have come up in the course of the pilot, in the course of the round tables, in our weekly discussions with our NIH partners. So that is what FDP does and aims to do, is to provide that information to the community in a collaborative way. We can't be successful on our own. We have to be successful together with NIH and with our funding partners. So thank you to NIH for your participation and all of your guidance. Jim or Melissa, any additional comments?

Jim Luther: My only comment is the same thing that I've said in these prior discussions. Being a member of the pilot means you get some real frank opportunities to sit down with NIH and have these discussions. It's a great opportunity to influence hopefully what the future is, ensure that the communication and FAQs and samples are out there. So again, I encourage everybody to talk to their institutions today, but also as we go into the costing discussions as well. Thank you.

Michelle Bulls: And I don't have much else to add except for, I just really enjoy the opportunity to partner with FDP and with all of you. And with others within the enterprise to just provide a

good way for us to collaborate and provide helpful feedback. And get helpful tips from one another. And just to develop a very comprehensive package and to show what real collaboration looks like. And how when we do it right both sides win and everybody's compliant.

Christi Keene: All right. I think, we can adjourn today's session. Thank you, everyone for your participation and please be on the lookout for more information in the future. Thank you.

Michelle Bulls: Thanks. Bye, everyone.

Melissa Korf: Thank you.